Quality Assurance in Spirometry

By Reed M. Gardner, PhD

Accurate and high-quality spirometry results should be the major objective of any person performing spirometry. By applying the principle of industrial quality control and other methods, we should be able to improve the quality of spirometric results and thus improve the quality of pulmonary health care.

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Webster's defines *quality* as "the degree of excellence" and *quality control* as "an aggregate of activities (as in design analysis and statistical sampling with inspection of defects) designed to ensure adequate quality, especially in manufactured products." Often, when discussing quality of a "product" such as spirometry we automatically assume that we are talking about high quality.

To measure spirometry quality we must use a requirement (standard) against which to compare it. For more than a decade, the American Thoracic Society (ATS) has been involved in making recommendations for standards for spirometry.[1]

Quality spirometry results are important because they are used to affect decisions about individual subjects or patients, such as: Does this subject have enough evidence of impaired lung function to preclude working at a specific job? Should steroid treatment be continued? Does this person qualify for disability compensation on the basis of impaired lung function? Should the subject's insurance status be changed? These questions indicate the importance of providing accurate and high quality spirometric results.

In recent years, quality assurance has been a focus of the industrial quality control literature.[2] A new theory, industrial quality control, has emerged. This theory states that to achieve high quality and lower cost: (1) Inappropriate variation must be eliminated, and (2) continuous improvement documented.[3]

Quality theory uses requirements—those explicit, measurable statements about the results a process is designed to achieve—to understand and eliminate inappropriate variation. Although requirements have a long history of successful use in medicine, quality theory expands their uses into a system of quality and cost control.

This new theory has implications for spirometry. The large and inappropriate variability in spirometric results has been long recognized. By applying the fundamental principles of quality control, inappropriate variation must be eliminated and continuous improvement documented. This seems possible, but requires an understanding of the sources of variation, establishment of reasonable requirements, and elimination of undesirable variability.

Spirometric Instrumentation

In retrospect, the principles of industrial quality control have been in effect for spirometry for about 15 years. The first specifications for spirometers as instruments were initiated by the American College of Chest Physicians (ACCP) in 1975.[4] At that time, pulmonary function investigators recognized that spirometric instrumentation was contributing to "inappropriate variation" in test results. The ATS followed up on the ACCP recommendations and refined instrument specifications and established several specifications for spirometric test performance, such as how to perform the test and make the measurements.[5] The ATS has since revised its recommendations in an attempt to achieve "quality"

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results.[1] Such action corresponds to the industrial quality control principle of "measuring continuous improvements."

Has continuous improvement been documented? Investigating the results of performance evaluations for spirometric instruments, some improvements have been made. When 19 spirometers were tested in 1980, only 10 (53%) of the devices met established specifications.[6] At that time, however, none of the 7 flow-meter type spirometers was acceptable. Recent testing of 62 spirometers showed that 35 (57%) met specifications, including 12 of 29 (41%) of the flow meters.[7] Spirometry instruments have improved, but at a disappointingly slow pace. As a consequence, even today, the spirometer purchaser should beware.

Table 1. Equipment Validation for 3-L Syringe Testing.

1. Check at least daily
2. Check at least every 4 hours during screening surveys
3. Check for leaks daily
4. Check FVC at slow (greater than 6 second emptying time) and fast (0.5 to 1 second emptying time)
5. Check volume over the entire range of volume spirometer quarterly

Equipment Validation

After a spirometer that meets ATS recommendations has been purchased, it is important to be certain that the spirometer continues to perform properly. This can be monitored using two methods.[1] The first is to use a 3-L syringe and test the spirometer (Table 1). The second is to keep a log book on the FVC and FEV_1 performances of a "known" subject, usually one of the laboratory personnel.[1]

Calibration checking with a 3-L syringe, as recommended by the ATS, is crucial to circumvent the variety of factors that can contribute to the variability of spirometry results. In addition to reducing or establishing variability between two instruments, calibration testing with the 3-L syringe can also help find leaks in spirometer systems. Calibration errors and leaks may cause a spirometer that initially measures accurately within the ATS requirements to be at a performance level well outside the acceptable limits. A leak will generally cause a spirometer to record volumes that are too small, particularly the FVC. Table 1 lists recommendations for testing with a 3-L syringe.[1]

Spirometric Test Performance

The largest remaining source of spirometric variability is the procedure for performing the spirometric maneuver. Because spirometry is an effort-dependent test, the operator/technician must be able to obtain the best effort.

During spirometry, a complex interaction occurs between the subject, the subject's physiologic condition, the instrumentation, and the personnel performing the test. To minimize the effects of each of these factors, standardized procedures have been developed to permit the best estimate of the test subject's condition. Procedural factors include: (1) Preparing the patient; (2) demonstrating the maneuver; (3) being a "cheerleader"; (4) watching the patient, and (5) recognizing unacceptable maneuvers.

The National Institutes of Occupational Safety and Health (NIOSH) and several professional organizations (the American Thoracic Society, The European Commission for Coal and Steel, the California Thoracic Society, and the Intermountain Thoracic Society) have recognized the role of performance procedure in reducing variability of spirometry results and standardized procedural factors.[1, 8-13] Several texts and articles also address procedural issues.[8,13]

In recent years, the detailed requirements for obtaining acceptable and reproducible spirometric results have been outlined by the ATS (Tables 2 and 3). Those interpreting spirometry should first assess the quality of the data before any interpretation is presented. Appropriate feedback should also be given to technicians to ensure that the best possible spirometry data are collected.

Other Sources of Variability

Personnel

Because the ATS recognized the need to have competent, well-trained personnel performing pulmonary function tests, they published a document entitled "Pulmonary Function Laboratory Personnel Qualifications."[14] Personnel must understand the pulmonary physiology and instrumentation, and interact well with test subjects to enhance test results.

Computers

Computers used with spirometers can provide tremendous advantage by reducing the time needed to acquire spirometry data, standardizing the measurement of the results, correcting for imperfections in the linearity of some devices, and reducing measurement errors.[10] Unfortunately, computers are not infallible. In a recent testing of 62 contemporary spirometers, we found that 95% were computerized and

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Table 2. Acceptability Requirements.

This test must have a minimum of 3 acceptable tests from a maximum of 8 attempts.

1. Satisfactory start of test
2. No cough in first second of test
3. No Valsalva's maneuver
4. An expiration time of at least 6 seconds or a flat volume-time plateau of 2 seconds
5. No leaks
6. No evidence of mouthpiece obstruction
7. A back extrapolated volume less than 5% of FVC or 100 mL, whichever is greater
8. Room temperature between 17 and 40°C

Table 3. Reproducibility Requirements Applied After Acceptability Requirements Have Been Met.

1. All 3 FVC levels within 5% of each other (or 100 mL, whichever is greater)
2. All 3 FEV_1 levels within 5% of each other (or 100 mL, whichever is greater)

that, initially, 25% had computer software errors. Therefore, being certain that the software is appropriate is just as important as knowing that the hardware is accurate.

The ATS has made the following recommendations about spirometry software:

1. Ensure that the software is correct by seeking verification from the manufacturer that an independent group certifies that the hardware and software measures the 24 standard testing waveforms accurately[1]
2. Obtain software flow charts for the measurement methods and documentation of the reference equations
3. Keep a log book of software revisions and note the enhancements made by the manufacturer or distributor. Keep a backup floppy disk copy of the software, where possible
4. Verify system performance using a "test subject" and comparing the results obtained by hand with the results from the computer display

Selection of Reference Values

A recent study by the author reviewing reference (normal) values for 28 different pulmonary function laboratories in the US found large variability in the reference values for FVC. Table 4 shows that reference values had more variability than the measured FVC.

Clearly a need exists to reduce variability of reference values for FVC. The variability of $\pm$ 0.2 L in the measured FVC (mean of about 5.0 L) is $\pm$ 4.0% of the measured value. This shows that the ability to accurately measure FVC at several institutions was quite good. Hankinson has also shown that the spirometer instrumentation and measurement technique used with a trained subject can measure FVC accurately.[1] However, a major problem remains with the reference value range. If we assume that the mean value of reference value FVC was 4.9 L, then there is an unacceptable variability of 0.6 L to either side or a range of $\pm$ 12.2%. Thus, we must improve the development and use of predicted values for spirometry. Until detailed recommendations are formulated on use and selection of predicted values at a minimum, each laboratory should: (1) Use predicted values for spirometry that are all derived from the same study (do not take an FVC predicted value from one study and an FEV_1 from another study); (2) each laboratory should check several of their staff or normal subjects and "validate" that the predicted values are reasonable.

Interpretation of Results

Several strategies have been developed to interpret spirometric results.[13,15] At the moment, however, no "standards" for interpretation have been recommended. The ATS currently has a committee working on development of "standard strategies" for making interpretations. Crucial to the process of making appropriate interpretations is selecting appropriate spirometric results from which to make the interpretations. Table 5 lists criteria for selecting spirometric results to be used for interpretation.[1]

Conclusions

Standardization of spirometric instrumentation has had a salutary effect on reducing variability of results. Standardization of testing methodology and definitions of measurements has also reduced variability of test results. Standardization of spirometric measurement methods has probably been effective in reducing variability of results from clinical laboratories.

Table 4. Reference Value and Measured FVC Variability for the Same Subject at 28 US Pulmonary Laboratories.

Test	Reference Value Range	Measured Range
FVC	4.3-5.5 L	4.8-5.2 L
Range variability	1.2 L	0.4 L

Table 5. Selection of Results for Interpretation.

1. Performed with a spirometer that meets ATS accuracy recommendations
2. Start of test—determined by back extrapolation
3. Largest FVC and largest FEV_1 are reported
4. The "best curve" is the one with the largest FVC + FEV_1

Training of personnel and use of computers has also added to improving the quality of spirometric results. However, improvement in the selection of reference values and interpretive strategies used is needed.

Determining accurate and high-quality spirometry results should be the major objective of any person performing spirometry. By applying the principle of industrial quality control and the methods outlined here, we should be able to improve the quality of spirometric results and thus improve the quality of pulmonary health care. ❐

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